PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 14 June 2000 (14.06.00)	
International application No. PCT/AU99/00929	**Applicant's or agent's file reference** 2226554/TDO
International filing date (day/month/year) 27 October 1999 (27.10.99)	**Priority date** (day/month/year) 27 October 1998 (27.10.98)
Applicant SCHOFIELD, Louis et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

25 May 2000 (25.05.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

INTERNATIONAL SEARCH REPORT

nternational Application No.
PCT/AU 99/00929

Box 1 Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

B x II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

The feature common to all of the claims is a glycosylphosphatidylinositol (GPI) which is capable of interacting with a CDI on an immune cell to form an association with CDI which association activates helper T cells. However, this common feature is generic in the art. Consequently, the common feature does not constitute "a special technical feature" since it makes no contribution over the prior art. Since there exists no other common feature which can be

continued on extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00929

Box II (continued)

considered as a special technical feature, no technical relationship between the different inventions can be seen. Consequently, it appears that a posteriori, the claims do not satisfy the requirement that they relate to one invention only.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00929

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member
WO	99/52547	NONE

END OF ANNEX

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00929

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61K 31/72, 31/73, 39/015, 39/008, 121:00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT; CAPLUS; MEDLINE:CDI, Glycosylphosphatidylinositol and T-Cell

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	WO 99/52547 (BRIGHAM WOMEN'S HOSPITAL INC.) EPD 13 April 1993 A61K 39/04, 39/39 OPI 21 October 1999. Page 3, lines 9-21 and Claims 14, 29 and 30	1-72
X,Y	Nagata, Norikazu; Taketani, Shigeru; Adachi, Yasushi; Hosaka, Naoki; Miyashima, Shigeo; Tokunga, Rikio; Ikehara, Susumu. A monoclonal antibody reactive with a glycosylphosphatidyl inositol-anchored molecules on T-cells defines CD4+ T cells subsets. Eur J Immunology. Volume 25, No: 3 11193-6. 1993.	1-72

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 1999	23 DEC 1999

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No.: (02) 6285 3929	**A. WILCOX** Telephone No.: (02) 6283 2243

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00929

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	Schofield, Louis; McConville, Malcolm, J; Hansen, Diana; Campbell, A Stewart; Fraser-Reid, Bert; Grusby, Michael, J; Tachado, Souvenir D. CDld-restricted immunoglobulin G formation to GPI anchored antigens mediated by NKT cells. Science 1983, Volume 283, No: 5399:225-229.	1-72
X,Y	Joyce, Sebastian; Woods, Amina S; Yewdell, Jonathon W; Bennick, Jack R; DeSilva, A Darshan; Boesteanu, Alina; Balk Steven P; Cotter, Robert J; Brutkiewicz, Randy R. Natural Ligand of mouse CDIdl:cellular glycosylphosphatidylinositol. Science 1998 Volume 279, No: 5356:1541-1544.	1-72
X,Y	Masuda, T; Yonemura, Y; Fujimoto, K; Hidaka, M; Nagakura, S; Nakakuma, H; Hata, H; Sanada, I; Kawakita, M and Takatsuki, K. Establishment of a human T-cell line with deficient surface expression of glycosylphosphatidylinositol (GPI)-anchored proteins from a patient with paroxysmal nocturnal haemoglobinuria. British Journal of Haematology, 1994, Volume 87, No: 1:24-30.	1-72
X,Y	Del-Porto, P; Mami-Chouaaib, F; Bruneau, J M; Jitsukawa, S; Dumas, J; Harnois, M and Hercend, T. TCT.1, a target molecule for gammal delta T cells is encoded by an immunoglobulin superfamily gene (Blast-1) located in the CD-1 region of human chromosome 1. Journal of Experimental Medicine. 1991, Volume 173, No: 6:1339-44.	1-72
X,Y	Beckman, Evan M; Porcelli, Steven A; Morita, Craig T; Behar, Samuel A; Furlong, Stephen T and Brenner, Michael B. Recognition of a lipid antigen by CDI-restricted $\alpha\beta^+$ T cells. Nature. Volume 372:691-694 ,1994.	1-72
X,Y	Sieling, P. A; Chatterjee, D.; Porcelli, S A.; Prigozy, TI; Mazzaccaro, R J; Soriano, T; Bloom, B R; Brenner, M B; Kronenberg, M; Brennan, P J and Modlin, R L. CD-1-Restricted T Cell Recognition of Microbial Lipoglycan Antigens. Science .Volume 269:227-229, 1995.	1-72

09/830459
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CORRECTED VERSION

REC'D 29 MAY 2001
WIPO PCT

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2226554	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 99/00929**	International filing date *(day/month/year)* 27 October 1999	Priority Date *(day/month/year)* 27 October 1998
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[7] A61K 31/736; 39/015 ; 39/008.		
Applicant 1. WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **6** sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

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3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
25 May 2000	23 February 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer A. WILCOX Telephone No. (02) 6283 2243

CORRECTED VERSION

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages as originally filed,
pages , filed with the demand,
pages , received on with the letter of .

[ ] the claims, pages as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of .

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages received on with the letter of .

[ ] ~~the sequence listing part of the description:~~
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written ~~sequence~~ listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/fig

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

The feature common to all claims is a glycosylphosphatidylinositol (GPI), which is capable of interacting with CDI on a T-Cell to form an association with CDI, which association activates helper T-cells and is not novel in he light of documents cited in the International Search Report. The common feature is not considered to be "a special technical feature" because it lacks novelty in the light of publications cited in the International Search Report. A posteriori, the claims do not satisfy the requirement that they relate to one invention only.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons: As stated above.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**NONE**	**YES**
	Claims	**1-72**	**NO**
Inventive step (IS)	Claims	**NONE**	**YES**
	Claims	**1-72**	**NO**
Industrial applicability (IA)	Claims	**1-72**	**YES**
	Claims	**NONE**	**NO**

2. Citations and explanations (Rule 70.7)

Citations

WO 99/52547 (Brigham Women's Hospital Inc) EPD 13 April 1993; A61K 39/04, 39/39, Open for Public Inspection 21 October 1999
Page 3, lines 9-21 and Claims 14, 29 and 30

Nagata, Norikazu; Taketani, Shigeru; Adachi, Yasushi; Hosaka, Naoki; Miyashima, Shigeo; Tokunga, Rikio Ikehara, Susumu. A monoclonal antibody reactive with a glycosylphosphatidyl inositol-anchored molecules on T-cells subsets. Eur J Immunology, Volume 25, No 3:11193-6, 1993

Schofield, Louis; McConville, Malcolm J; Hansen, Diana; Campbell, A Stewart; Fraser-Reid, Bert; Grusby, Michael, J; Tachado, Souvenir D; CDId-restricted immunoglobulin G formation to GPI-anchored antigens mediated by NKT cells. Science, 1983, Volume 283, No: 5399:225-225

Joyce, Sebastian; Woods, Amina. S; Yewdell, Jonathon W; Bennick, Jack R; DeSilva, A Darshan; Boesteanu, Alina; Balk Steven P; Cotter, Robert J; Brutkiewicz, Randy R. Natural Ligand of mouse CDIdl:cellular glycosylphosphatidylinositol. Science, 1998, Volume 279, No:5356:1541-1544

Masuda, T; Yonemura, Y; Fujimoto, K; Hidaka, M; Nagakura, S; Nakakuma, H; Hata, H; Sanada, I; Kawakita, M and Takatsuki, K. Establishment of a human T-cell line with deficient surface expression of glycosylphosphatidylinositol (GPI)-anchored proteins from a patient with paroxysmal nocturnal haemoglobinuria. British Journal of Haematology, 1994, Volume 87, No: 1:24-30

Del-Porto, P; Mami-Chouaib, F; Bruneau, J M; Jitsukawa, S; Dumas, J; Harnois, M and Hercend, T. TCT.1, a target molecule for gamma delta T-cells is encoded by an immunoglobulin superfamily gene (Blast-1) located in the CD-1 region of human chromosome 1. Journal of Experimental Medicine, 1991, Volume 173, No: 6: 1339-44

Beckman, Evan M; Porcelli, Steven A; Morita, Craig T; Behar, Samuel A; Furlong, Stephen T and Brenner, Michael B. Recognition of a lipid antigen by CDI-restricted $\alpha\beta^{+}$T-cells. Nature, Volume 372:694, 1994

Sieling, P A; Chatterjee, D; Porcelli, S A; Prigozy, T I; Mazzaccaro, R J; Soriano, T; Bloom, B R; Brenner, M B; Kronenberg, M; Brennan, P J and Modlin, R L. CDI-Restricted T-Cell Recognition of Microbial Lipoglycan Antigens. Science, Volume 269: 227-229, 1995

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims are not fully supported by the description because there is no disclosure in the specification supporting a claim to a method of activating helper T-cells using all the variants of glycosylphosphatidylinositol included in the scope of the claims.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : **BOX V**

Explanations

The essential features of Claims 1-72 are a composition comprising a GPI, which is capable of interacting with CDI to form an association with CDI, which association activates helper T-cells. Claims 9-10 are directed to a GPI derived from Plasmodium sp. or Plasmodium falciparum. The cited publications all disclose immunogenic or vaccine composition comprising a CDI or lipid antigen, which is a glocosylphosphatidyllinositol (GPI) or GPI complex capable of interacting with a CDI to form an association, which activates helper T-cells.

WO 99/52547 and Schofield (1999) were published prior to the international filing date but later than the claimed priority date and no comment is included for novelty and inventive step although both documents disclose the claimed invention.

Joyce et al. (1998) discloses cellular glycosylphosphatidyl inositol as a natural ligand of CDIdl. The activation of the CDIdl receptor site controls the differentiation and function of a T-lymphocyte subset, NK1 + natural T-cells proposed to regulate immune responses. Masuda et al. (1994) disclose complexes of GPI and T-cell subsets such as CD4. Sieling et al. (1995) discloses GPI-CDI-mediated stimulation of T-cell subsets.

Claims 1-77 lack novelty and inventive step in the light of the previously cited publications.

A person skilled in the art would include the large number of possible GPI molecules listed in the applicant's claims within the common general knowledge. Publications by Del Porto et al. (1991) and Nagata et al. (1993) disclose analogous CDI-GPI activation of T-Cells. Such analogous processes are included in the scope of the claims.

The attorney has stated that the publications by Joyce et al. (1998), Masuda et al. (1994), Sieling et al. (1995), Del Porto et al. (1991) and Nagata et al. (1993) are not relevant for the purposes of novelty and inventive step on the basis of the inclusion of the feature of CD1-restricted T-cell activation in the cited publications. This feature is the essential feature of the claimed invention and all cited publication are considered to disclose the essential feature of the claims. Nagata et al. (1993) discloses a GPI anchored molecule specific for T-cells which defines CD4+T cells subsets and is implicated in T-cell activation. Masuda et al. (1994) discloses GPI stimulated T-cell activation which has been tested for the presence of CD1 and discloses the testing approach defined in claim 1. Nagata et al. (1993) has been cited because it describes a mechanical equivalent and Masuda et al. (1994) discloses a routine testing approach equivalent to the process defined in claim 1. A person skilled in the art would test for reactivity with CD1 during T-cell activation in the light of the disclosure in Masuda et al. (1994). Claim 1 requires a testing process to show which GPI molecules react with CD1 to activate T-cells.

Del Porto et al. (1991) discloses that a molecule know as TCT.1/Blast 1 anchors to the cell membrane via a GPI containing lipid and is involved in specific T-cell recognition. Cytogenetic studies (page 1342, column 2) show that Blast-1 gene is located in the same position as CD1 gene which is known to produce specific T-cell responses.

Beckman et al. (1994) discloses that a CD1b molecule presents a lipid antigen, mycolic acid which is derived from Mycobacterium tuberculosis, in the process of T-cell activation. Seiling et al. (1995) discloses CD1 mediated T-cell activation via presentation of an antigen fraction which include GPIs. The attorney has not commented on the specific details of the cited publications.

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61K 31/72, 31/73, 39/015, 39/008 // 121:00

A1

(11) International Publication Number: WO 00/24406

(43) International Publication Date: 4 May 2000 (04.05.00)

(21) International Application Number: PCT/AU99/00929

(22) International Filing Date: 27 October 1999 (27.10.99)

(30) Priority Data:
PP 6758 27 October 1998 (27.10.98) AU

(71) Applicant *(for all designated States except US)*: THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH [AU/AU]; Royal Parade, Parkville, Victoria 3052 (AU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: SCHOFIELD, Louis [AU/AU]; 185 Panorama Drive, Gisborne, Victoria 3437 (AU). HANSEN, Diana [AR/AU]; 5 Ladner Court, Chadstone, Victoria 3148 (AU).

(74) Agents: HUGHES, E., John, L. et al.; Davies Collison Cave, 1 Little Collins Street, Melbourne, Victoria 3000 (AU).

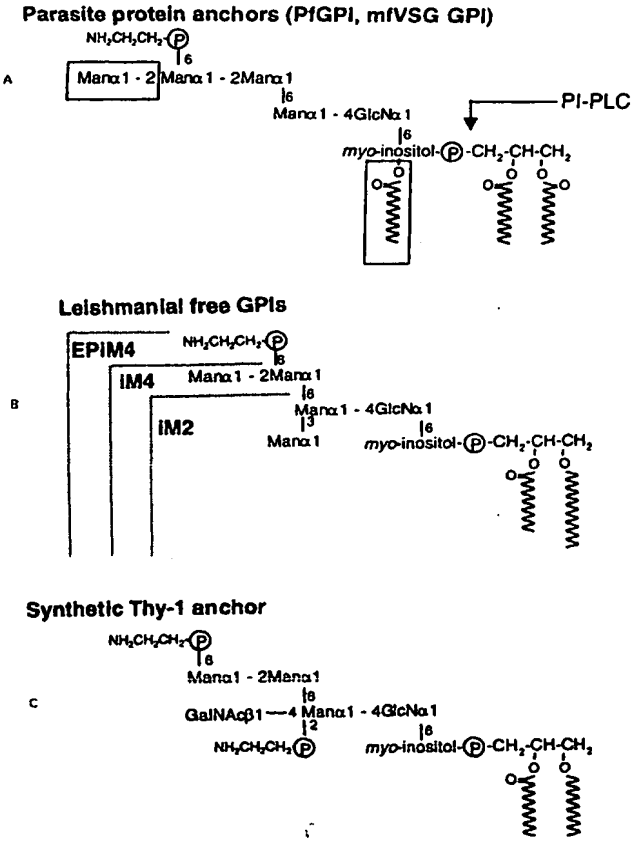
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: A METHOD OF ACTIVATING T CELLS AND AGENTS USEFUL FOR SAME

(57) Abstract

The present invention relates generally to a method of activating T cells and more particularly to a method of activating T cells using glycosylphosphatidylinositol (referred to herein as "GPI") molecules and derivatives or equivalents thereof. Even more particularly the method of the present invention contemplates a method of activating T cells, using GPI molecules, via a CD1–restricted pathway. The method of the present invention is useful, *inter alia*, in a range of therapeutic and/or prophylactic applications including, but not limited to applications which require skewing of the TH1/TH2 response or which require the induction of antibody production.



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